ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-13- 19075	88130000233	4/22/13

COMMENTS:

DOES NOT CONTAIN CBI

3M Environmental, Health and Safety Operations

3M Center, Building 0224-05-W-03
St. Paul, MN 55144-1000

MR#353572

Certified Mail

April 15, 2013

NO CBI

Document Processing Center
EPA East – Room 6428 Attn: Section 8(e)
Office of Pollution Prevention and Toxics, U.S. EPA
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: TSCA 8(e) Substantial Risk Notice on CAS 12513-42-7; octadecaborane (lot/batch #B18-05009)

To whom it may concern:

The objective of this submission is to inform the EPA of data suggesting an acute oral LD50 of 93 mg/kg for CAS 12513-42-7; octadecaborane (lot/batch #B18-05009). 3M became aware of these data while conducting routine data collection as part of an overall integration effort for Ceradyne, Inc.

Ceradyne was acquired by 3M in November of 2012. The data in question were generated by SemiEquip Materials, Inc., a Ceradyne company, prior to being acquired by 3M. Integration of Ceradyne into 3M will address all aspects of 3M's TSCA 8(e) review and reporting procedures.

The final study report for the data in question is enclosed.

If you have any questions or would like any additional information, please contact Deanna Luebker, 3M TSCA 8(e) Coordinator, at (651) 737-1374 or djluebker@mmm.com.

Sincerely,

Jean B. Sweeney (DL)

Jean B. Sweeney
Staff Vice President, 3M Environmental, Health and Safety Operations

CONTAINS NO CBI

MB Research Laboratories

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

VOLUME I

Study Title	:	Acute Oral Toxicity - Up and Down Procedure (UDP)
Test Article	:	Octadecaborane, Lot/batch #B18-05009
Data Requirements	:	EPA 40 CFR 158.340, Guideline Reference OPPTS 870.1100
Author	:	Daniel R. Cerven, M.S., Study Director
Study Completed On	:	March 14, 2006
Performing Laboratory	:	MB Research Laboratories 1765 Wentz Road P.O. Box 178 Spinnerstown, PA 18968
MB Research Project #	:	MB 05-14045.01
MB Research Protocol #	:	1010-01
Sponsor	:	SemEquip Materials, Inc. 1721 Lower Water Street Halifax, NS, Canada B3J 1S5
Citation	:	Daniel R. Cerven, M.S. (2006) Unpublished Report by MB Research Laboratories

Attachment 11

Study Title : **Oral Toxicity in Rats (UDP)**
Project # : **MB 05-14045.01**
Test Article : **Octadecaborane, Lot/batch #B18-05009**
Protocol : **1010-01**

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in the above study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B) or (C).

COMPANY : SEMEQUIP MATERIALS, INC.

COMPANY AGENT : _____

TITLE : _____

SIGNATURE : _____

DATE : _____

Study Title	:	**Oral Toxicity in Rats (UDP)**
Project #	:	**MB 05-14045.01**
Test Article	:	**Octadecaborane, Lot/batch #B18-05009**
Protocol	:	**1010-01**

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B) or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the above study.

COMPANY : SEMEQUIP MATERIALS, INC.

COMPANY AGENT : _____

TITLE : _____

SIGNATURE : _____

DATE : _____

Study Title	:	**Oral Toxicity in Rats (UDP)**
Project #	:	**MB 05-14045.01**
Test Article	:	**Octadecaborane, Lot/batch #B18-05009**
Protocol	:	**1010-01**

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practices Regulations of the EPA 40 CFR 160 and 792, FDA 21 CFR 58, and as specified in The Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997

SUBMITTER : SEMEQUIP MATERIALS, INC.

_____
Signature Date

SPONSOR : SEMEQUIP MATERIALS, INC.

_____
Signature Date

STUDY DIRECTOR : 14 Mar 06
Daniel R. Cerven, M.S. Date
MB RESEARCH LABORATORIES

PROJECT NUMBER : MB 05-14045.01
TEST ARTICLE : Octadecaborane, Lot/batch #B18-05009
SPONSOR : SEMEQUIP MATERIALS, INC.
TITLE : Acute Oral Toxicity - Up and Down Procedure (UDP)
PROTOCOL # : 1010-01

A B S T R A C T

Objective: To determine the potential for toxicity of the test article when administered orally. This study is designed to comply with the standards set forth in EPA Health Effects Test Guidelines, OPPTS 870.1100 December 2002, and in OECD Guidelines for the Testing of Chemicals, Guideline 425 adopted December 17, 2001.

Method Synopsis: Initially, a single female Wistar rat was dosed orally with Octadecaborane, Lot/batch #B18-05009 at a dose level of 2000 mg/kg. Since the animal died, additional animals were dosed, one at a time, by a single ordered dose progression as indicated in the chart below. The rats were observed 1/2, 1, 2 and 4 hours postdose and once daily for 14 days for toxicity and pharmacological effects. All animals were observed twice daily for mortality. Body weights were recorded immediately pretest, weekly, at death and at termination in the survivors. All animals were examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histological examination. The potential for toxicity was based on the mortality response noted. The LD_{50} and 95% Confidence Limits were calculated using AOT425 Stat Pgm provided by the EPA.

Summary:

Mortality responses to the oral dosing was:

Animal #	Dose mg/kg	Response (O=alive, X=dead)
1/F	2000	X
2/F	550	X
3/F	175	X
4/F	55	O
5/F	175	X
6/F	55	O
7/F	175	X
8/F	55	O

The deaths occurred within 3 days of dosing and were preceded by predeath physical signs of diarrhea, wetness of the anogenital area, few feces, lethargy, ataxia, prostrate, tremors, chromorhinorrhea, soiling of the anogenital area, chromodacryorrhea, emaciation, nose/mouth area stained red, body temperature appeared colder than normal and sagging eyelids. Necropsy results of these animals revealed abnormalities of the lungs, heart, liver, thymus, spleen, kidneys and gastrointestinal tract as well as chromodacryorrhea, chromorhinorrhea, red staining of the nose/mouth area, wetness of the nose/mouth area, yellow staining of the anogenital area and wetness and soiling of the anogenital area.

There were no abnormal physical signs noted in the survivors (all dosed at 55 mg/kg). Body weight changes and necropsy results in the survivors were normal.

Conclusion: The LD_{50} and 95% Confidence Limits are 93 (55 - 175) mg/kg.

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-14045.01
Test Article : Octadecaborane, Lot/batch #B18-05009
Protocol : 1010-01

OBJECTIVE

To determine the potential for toxicity of the test article when administered orally. This study is designed to comply with the standards set forth in EPA Health Effects Test Guidelines, OPPTS 870.1100 December 2002, and in OECD Guidelines for the Testing of Chemicals, Guideline 425 adopted December 17, 2001

TEST ARTICLE

Identity		Octadecaborane, Lot/batch #B18-05009
Test Article Characterization		See Appendix A for Test Article Characterization.
Stability		The test article is stable at room temperature indefinitely according to the Test Article Characterization.
Supplied by		SemEquip Materials, Inc
Date Received	:	09/02/05
Storage	:	Room temperature and humidity
Description	:	Solid powder off-white
Specific Gravity	:	Not applicable
Sample Preparation	:	The test article was used as a 25% concentration in corn oil.

TEST DATES

Study Initiation	(date protocol signed)	:	11/02/06
Experimental Start Date	(1st exposure to test substance)	:	11/03/06
Experimental Term Date	(last date data collected)	:	01/27/06
Draft Report Signed	(if applicable)	:	02/22/06
Final Report Signed	(study completion)	:	03/14/06

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 09/20/05, 11/03/05, 11/08/05, 11/15/05, 12/01/05, 12/06/05 & 12/13/05. Following an equilibration period of at least five days, eight healthy, non-pregnant and nulliparous female Wistar albino rats were assigned to treatment groups without conscious bias.

The animals were born the weeks of 07/26/05, 09/15/05, 09/20/05, 09/27/05, 10/06/05, 10/11/05 & 10/18/05. The pretest body weight range was 152 - 229 grams. The weight variation of one animal (#3) used did exceed ± 20% of the mean initial weight of all previously dosed animals.

The animals were identified by cage notation and indelible body marks, and housed in suspended wire mesh cages; 1/cage. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12 hour light/dark cycle, and was kept clean and vermin free.

EXPERIMENTAL DESIGN (continued)

Dosing

The test article was mixed with corn oil to make dosing by gavage possible. The dose was based on the dry weight of the test article. Initially, a single female Wistar rat was dosed orally by syringe and dosing needle at a dose level of 2000 mg/kg. Since the animal died, additional animals were dosed, one at a time, by a single ordered dose progression.

Type and Frequency of Observations

In Vivo - Animals were observed 1/2, 1, 2 and 4 hours postdose and once daily for 14 days for toxicity and pharmacological effects. All animals were observed twice daily for mortality. Body weights were recorded immediately pretest, weekly, at death and at termination in the survivors.

Post Mortem – All survivors were humanely sacrificed using CO_2 following study termination and examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histological examination.

Analysis of Data

The LD_{50} and 95% Confidence Limits were calculated using AOT425 Stat Pgm provided by the EPA.

Retention of Data

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number. The preserved tissues are stored at MB Research by sponsor name and MB project number. The sponsor will be contacted for final disposition of the tissues upon submission of the report.

The test article will be returned to the sponsor following submission of the report.

Amendment to the Protocol

There were no amendments to the protocol.

Deviation to the Protocol

The following Deviations were noted and the affect on the outcome of the study is unknown:

1) Animal #1 was 14 weeks of age instead of 8-12 weeks of age at study initiation.
2) The body weight for animal #1 was not recorded at death.
3) The ½ hour and 1 hour systemic observation was performed after the allowable time period on animal #5.
4) The body weight for animal #3 was outside the ± 20% of the previously dosed animals.

RESULTS & DISCUSSION

1. Mortality, Body Weights, Systemic Observations & Necropsy Findings (Tables 1 - 3)

Mortality responses to the oral dosing was:

Animal #	Dose mg/kg	Response (O=alive, X=dead)
1/F	2000	X
2/F	550	X
3/F	175	X
4/F	55	O
5/F	175	X
6/F	55	O
7/F	175	X
8/F	55	O

The deaths occurred within 3 days of dosing and were preceded by predeath physical signs of diarrhea, wetness of the anogenital area, few feces, lethargy, ataxia, prostrate, tremors, chromorhinorrhea, soiling of the anogenital area, chromodacryorrhea, emaciation, nose/mouth area stained red, body temperature appeared colder than normal and sagging eyelids. Necropsy results of these animals revealed abnormalities of the lungs, heart, liver, thymus, spleen, kidneys and gastrointestinal tract as well as chromodacryorrhea, chromorhinorrhea, red staining of the nose/mouth area, wetness of the nose/mouth area, yellow staining of the anogenital area and wetness and soiling of the anogenital area.

There were no abnormal physical signs noted in the survivors (all dosed at 55 mg/kg). Body weight changes and necropsy results in the survivors were normal.

Study Title	:	**Oral Toxicity in Rats (UDP)**
Project #	:	**MB 05-14045.01**
Test Article	:	**Octadecaborane, Lot/batch #B18-05009**
Protocol	:	**1010-01**

CONCLUSION

The LD_{50} and 95% Confidence Limits are 93 (55 - 175) mg/kg.

FINAL REPORT

Approved by: _____ 14 Nov 06

Daniel R. Cerven, M.S. Date
Study Director

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-14045.01
Test Article : Octadecaborane, Lot/batch #B18-05009
Protocol : 1010-01

Table 1: Dose Volume and Body Weights in grams

An. #	Sex	Dose mg/kg	Dose Volume in cc	Body weight in grams Day 0	Day 7	Day 14
1	F	2000	1.8	229		
2	F	550	0.38	172		
3	F	175	0.11	152		
4	F	55	0.041	188	221	251
5	F	175	0.12	175		
6	F	55	0.040	180	215	237
7	F	175	0.13	185		
8	F	55	0.046	210	251	264

No entry indicates animal died before observation period.

Table 2: Systemic Observations

TOXICITY CODE

B	=	Lethargy
D	=	Diarrhea
E	=	Ataxia
G	=	Prostrate
J	=	Chromodacryorrhea
O	=	Tremors
Q	=	Sagging eyelids
R	=	Anogenital area wet
S	=	Chromorhinorrhea
T	=	Anogenital area soiled
W	=	Appears emaciated
X	=	Few feces
Z	=	Dead
1	=	Nose/mouth area stained red
2	=	Body temperature appeared colder than normal

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-14045.01
Test Article : Octadecaborane, Lot/batch #B18-05009
Protocol : 1010-01

Table 3: Necropsy Observations

DOSE – mg/kg	2000	550	175	55	175	55	175	55
Animal number/Sex	1/F	2/F	3/F	4/F	5/F	6/F	7/F	8/F
Observations	D	D	D	S	D	S	D	S
Normal				X		X		X
Chromadacryorrhea							3	
Chromorhinorrhea							2	
Nose/mouth: stained red					2			
Nose/mouth: wet	3							
Anogenital area: stained yellow			1					
Anogenital area: soiled					2		2	
Anogenital area: wet	3	3						
Lungs: darker than normal	2	2	3					
Lungs: red areas	2	2	3				3	
Heart: pale areas	1							
Liver: pale areas	2				2			
Liver: darker than normal	2							
Kidneys: pale areas	1						1	
Stomach: red areas			2		2			
Stomach : pale	3						2	
Stomach: distended with gas	3							
Spleen: darker than normal	2		2				2	
Intestines: red areas							2	
Intestines: distended with mucus					2		1	
Intestines: yellow areas					1		2	
Stomach: yellow grainy material			2					
Thymus: darker than normal	2				2		2	
Thymus: dark areas			2					

CODES: D = death
S = sacrifice
X = observed

1= slight or scattered
2= moderate or few
3= pronounced or many

Study Title : **Oral Toxicity in Rats (UDP)**
Project # : **MB 05-14045.01**
Test Article : **Octadecaborane, Lot/batch #B18-05009**
Protocol : **1010-01**

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. No deviations from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to Mgmt.	Sty. Dir.
11/03/05	Sample preparation	Erin Range	03/13/06	03/14/06
02/13/06	Raw data audit	William J. Kintigh	03/13/06	03/14/06
02/22/06	Draft report audit	William J. Kintigh	03/13/06	03/14/06
03/10/06	Final report audit	William J. Kintigh	03/13/06	03/14/06

William J. Kintigh 14 MAR 2006
William J. Kintigh, B.S. Date
Quality Assurance Unit

MB Research Laboratories

1755 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

TEST ARTICLE CHARACTERIZATION INFORMATION

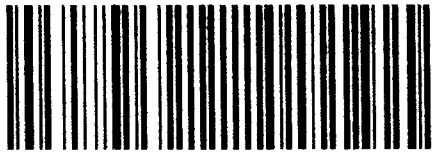
Characterization of the test article is required in support of data submissions and should include identity, strength, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2). Accordingly, please supply the following information for each test article submitted:

- Test Article Identity : Octadecaborane.
- Strength : Not Applicable
- Purity : 98% +
- Composition : $B_{18}H_{22}$
- Stability : Stable at room temp. indefinately
- Uniformity : Homogeneous

BY: [signature] 26oct05 (signature) (date) FOR: SEMEQUIPMATERIALS 26oct05 (company) (date)

Deanna Luebker, PhD
CT&RS 220 6E 03
651 737 1374

3M General Offices
3M Center
St Paul, MN 55144-1000



7010 1670 0000 0225 2632